

### **REMARKS/ ARGUMENTS**

Claims 1-28 are pending in the current application. Claim 9 has been amended. Applicants address each of the rejections below, in the order in which they are presented in the Office Action.

#### **Claim Rejections Have Been Addressed**

##### **Second Paragraph, 35 U.S.C. 112**

Claim 9 was rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants have removed the i.e. phrase from Claim 9. Applicants respectfully submit that the foregoing amendment overcomes the Examiner's rejection, and withdrawal is respectfully requested.

##### **35 U.S.C. 103(a)**

***Claims 1, 2 and 5 to 15 are patentable over Anderson et al (5,471,001).***

Claims 1, 2 and 5 to 15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (5,471,001).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.<sup>1</sup> M.P.E.P. § 2142.

Applicant respectfully submits that the Patent Office has not established a *prima facie* case of obviousness for at least the reason that the Patent Office has not proven that the Anderson et al teaches or suggests all the claim limitations.

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<sup>1</sup> Because all three criteria must be met in order to establish a *prima facie* case of obviousness, and criterion (3) that the prior art reference (or references when combined) must teach or suggest all the claim limitations has not been met, Applicant addresses this criterion without discussion of the other criteria, namely (1) that there must be some suggestion or motivation to modify the reference or combine reference teachings and (2) whether there is a reasonable expectation of success. Applicant's decision not to discuss these criteria is in no way an acquiescence that these criteria have been proven by the Patent Office, and Applicant expressly reserves the right to address these criteria in future responses, should the need arise.

Anderson et al do not teach:

A process for preparing crystalline particles of substance which comprises mixing in a continuous flow cell in the presence of ultrasonic radiation a flowing solution of the substance in a liquid solvent with a flowing liquid anti-solvent for said substance, and collecting the resultant crystalline particles generated, characterised in that the solution and anti-solvent are delivered into the continuous flow cell in parallel contacting streams.

Anderson et al relates to a process for the crystallization of adipic acid which comprises subjecting an aqueous mother liquor containing dissolved adipic acid to ultrasonic agitation (column 1, lines 5-19, column 2, line 64 – column 3, line 63). Anderson et al do not describe a process which comprises mixing in a continuous flow cell a flowing solution of the substance in a liquid solvent with a flowing liquid anti-solvent for said substance. Not only do Anderson et al not describe use of a continuous flow cell nor the use an antisolvent, but Anderson et al also do not describe mixing the flowing solution of the substance and solvent with the flowing solution of liquid antisolvent in parallel contacting streams.

The Office Action states that “in the absence of unexpected results, it would have been obvious to one of ordinary skill in the art to determine through routine experimentation the optimum, operable feed means and controls in the Anderson et al reference in order to allow for proper mixing prior to the solution being affected by the ultrasonic device and to regulate the flow of materials in the and out of the chamber.” The Office Action has not established that there is a design need or market pressure to solve a problem in Anderson et al and that a finite number of identifiable, predictable solutions exists, such that a person ordinary skill has good reason to pursue other options. Furthermore, even if one of ordinary skill tried other operable feed means and controls, one of ordinary skill would not obtain Applicant’s invention. For example, Applicant’s process includes an additional solution, an anti-solvent for said substance, which is introduced in a parallel contacting stream with the flowing solution of the substance in a liquid solvent. Therefore, Anderson et al do not teach or suggest all the claim limitations. For at least the foregoing reasons, Applicant respectfully submits that Claim 1 is patentable.

Anderson et al also do not teach an apparatus as recited in Claim 2:

An apparatus for preparing crystalline particles of a substance which comprises:

- (i) a first reservoir of said substance dissolved in a liquid solvent;
- (ii) a second reservoir of liquid anti-solvent for said substance;
- (iii) a mixing chamber having first and second inlet ports and an outlet port;
- (iv) means for delivering the contents of the first and second reservoirs to the mixing chamber via the first and second inlet ports respectively at independent controlled flow rate, which first and second inlet ports are orientated such that the contents of the first and second reservoirs are delivered into the mixing chamber in parallel contacting streams;
- (v) a source of ultrasonic radiation located in the vicinity of the first inlet;

and

- (vi) means for collecting particles suspended in the liquid discharged from the mixing chamber at the outlet port.

As discussed above, Anderson et al do not teach use of an antisolvent. Furthermore, Anderson et al do not teach a reservoir of a liquid anti-solvent, a mixing chamber have a first and second inlet ports, means for delivering the contents of the first and second inlet ports at independent controlled flow rates, nor inlet ports oriented such that the contents of the first and second reservoirs are delivered in parallel contacting stream. Anderson et al do not teach or suggest all the claim limitations. For at least the foregoing reasons, Applicant respectfully submits that Claim 2 is patentable.

Claims 5 to 15 each depend directly or indirectly from patentable independent Claim 2. For at least this reason and without acquiescing in the Office Action's rejections of these claims, Applicants respectfully submit that dependent Claims 5 to 15 are also patentable.

Accordingly, Applicant respectfully requests that the foregoing rejections be withdrawn.

***Claims 3, 4 and 16 to 28 are patentable over Anderson et al in view of Al-Ghazawi et al (2003/0203937).***

Claims 3, 4 and 16 to 28 were rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al (5,471,001) in view of Al-Ghazawi et al (2003/0203937).

Applicant respectfully submits that independent Claims 1 and 2 are patentable. Claims 3, 4 and 16 to 28 depend directly or indirectly from patentable independent Claims 1 or 2. For at least this reason and without acquiescing in the Office Action's separate rejection of these dependent claims, Applicant respectfully submits that Claims 3, 4, and 16 to 28 are also patentable. Accordingly, Applicant respectfully requests that this rejection be withdrawn.

It is respectfully submitted that the present application is in condition for allowance.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge any fees or credit any overpayment, particularly including any fees required under 37 CFR §1.16 or §1.17, and any necessary extension of time fees, to Deposit Account No. 07-1392.

Respectfully submitted:

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